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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,313	03/04/2002	Christine Dingivan	10271-063-999	7146

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EXAMINER
SKELDING, ZACHARY S

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,313	DINGIVAN, CHRISTINE	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,26-31,33-36,39,40,62,63,66,67,69 and 72-75* is/are pending in the application.

4a) Of the above claim(s) *67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,26-31,33-36,39,40,62,63,66,69 and 72-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-12-07 5-21-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments to the instant specification and claims, filed March 12, 2007 are acknowledged.

   Claims 1-5, 8-25, 32, 37, 38, 41-61, 64, 65, 68, 70 and 71 have been canceled.

   Claims 6, 7, 26, 29, 31, 33-36, 39, 40, 63, 66, and 69 have been amended.

   Claims 72-75 have been added.

   Claims 6, 7, 26-31, 33-36, 39, 40, 62, 63, 66, 67, 69 and 72-75 are pending.

2. Upon further consideration, "LFA3TIP" has been rejoined as a species of "one CD2 binding molecule" for claims reciting one or more CD2 binding molecules. Accordingly, the species of "one CD2 binding molecule" for claims reciting one or more CD2 binding molecules are "an anti-CD2 antibody" and "LFA3TIP".

   Thus, claims 6, 7, 26-31, 33-36, 39, 40, 62, 63, 66, 69 and 72-75 are under examination as they read on a method of treating an autoimmune disorder or inflammatory disorder comprising administering one or more CD2 binding agents and further comprising an anti-angiogenic factor, wherein the elected species are **"psoriasis", "anti-CD2 antibody", "LFA3TIP"** and **"anti-TNFα antibody"**.

   Claim 67 has been withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected invention.

3. This Office Action is in response to Applicant's amendments to the instant specification and claims, filed March 12, 2007.

   The rejections of record can be found in the previous Office Action, mailed October 11, 2006.

4. The objection to the instant specification is maintained because the instant specification recites "LFA-3TIP" while claim 30 recites "LFA3TIP", and regardless of which designation is used, consistent terminology should be used throughout the specification and claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

   > The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 30 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments have been considered but have not been found convincing, essentially for the reasons of record.

In particular, with respect to claims reciting, "wherein the fusion protein is LFA3TIP", applicant argues that the specification of the present application teaches "LFA3TIP" is available by Biogen, Inc. of Cambridge Massachusetts and that Wallner et al. (U.S. Patent No. 6,162,432), which issued on December 19, 2000 and is assigned to Biogen, Inc. (Cambridge, MA) et al., provides the amino acid and nucleotide sequences for "LFA3TIP" (see SEQ ID NO:7 of the '432 Patent). Applicant further argues that the '432 Patent states that the plasmid, pSAB 152, encoding LFA3TIP was deposited with the ATCC under Accession No. 68720. Thus, Applicant respectfully submits that one of skill in the art would have been able to ascertain the fusion protein referred to as "LFA3TIP."

Applicant's argument has been considered but has not been found convincing, essentially for the reasons of record.

It remains unclear exactly what is meant by the claim limitation, "wherein the fusion protein is LFA3TIP". According of the instant specification, "[i]n a specific embodiment, a CD2 binding molecule is ***LFA-3TIP (Biogen, Inc., Cambridge, MA).***" However, it remains unclear if the claimed "***LFA3TIP***" is the same as the "***LFA-3TIP of (Biogen, Inc., Cambridge, MA)***" disclosed in the instant specification.

Moreover, applicant has not established a nexus in the art, and there is no apparent nexus established by the instant specification, between the disclosure of "LFA-3TIP of (Biogen, Inc., Cambridge, MA)" in the instant specification and the patent of Wallner et al. (6,162,432) which provides the amino acid and nucleotide sequences for a fusion protein designated "LFA3TIP" and also discloses a plasmid encoding LFA3TIP ("pSAB 152") was deposited with the ATCC under Accession No. 68720.

Furthermore, in light of the other disclosure of the instant specification that various forms of the extracellular domain of LFA-3 may be fused to the Fc domain of an immunoglobulin, which the skilled artisan would also consider to be "LFA3TIP" fusion proteins (see, in particular page 84, 3rd paragraph to page 85, 1st paragraph) it is yet further unclear what is meant by the claimed limitation, "wherein the fusion protein is LFA3TIP".

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 7, 30, 33, 40 and 73, and dependent claims thereof, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments have been considered but have not been found convincing, essentially for the reasons of record.

A. "MEDI-507": Claims 7, 33, 40 and 73, and dependent claims thereof.

Applicant argues that the amino acid sequence of MEDI-507 was available to one of skill in the art as of the effective date of the present application in Bazin Examples 11 and Figures 31 and 42, and that techniques for producing MEDI-507 are described in the instant specification at page 153, line 7 to page 169, line 2. Thus, Applicant concludes the instant claims are enabled because one of skill in the art would have been able to obtain or make and use the "MEDI-507" antibody as claimed.

Applicant's argument has been considered but has not been found convincing, essentially for the reasons of record.

Applicant has not amended the claims to recite Deposit Accession Number for the "MEDI-507" antibody, and while Bazin discloses the sequence of the heavy and light chain variable regions of the "MEDI-507" antibody, it does not appear to disclose the sequence of the ***particular*** heavy and light chain ***constant regions*** found in the "MEDI-507" antibody.

Without the sequence of the ***complete antibody or a cell line encoding the antibody*** the skilled artisan could not make and use the claimed "MEDI-507" antibody, and thus, the instant rejection under 35 U.S.C. § 112, 1st paragraph, enablement is maintained.

B. "LFA3TIP": claim 30

Applicant argues that "LFA3TIP" is disclosed as SEQ ID NO: 7 of Wallner et al. (U.S. Patent No. 6,162,432) and therefore it is enabled.

Applicant's argument has been considered but has not been found convincing, essentially for the reasons of record.

As a preliminary matter, it remains unclear exactly what is meant by the claim limitation, "wherein the fusion protein is LFA3TIP". According of the instant specification, "[i]n a specific embodiment, a CD2 binding molecule is ***LFA-3TIP (Biogen, Inc., Cambridge, MA).***" However, it remains unclear if the claimed "***LFA3TIP***" is the same as the "***LFA-3TIP of (Biogen, Inc., Cambridge, MA)***" disclosed in the instant specification. If applicant

does not understand what is being claimed then applicant cannot possibly make and use the claimed biological material.

Moreover, applicant has not established a nexus in the art, and there is no apparent nexus established by the instant specification, between the disclosure of "LFA-3TIP of (Biogen, Inc., Cambridge, MA)" in the instant specification and the patent of Wallner et al. (6,162,432) which provides the amino acid and nucleotide sequences for a fusion protein designated "LFA3TIP" and also discloses a plasmid encoding LFA3TIP ("pSAB 152") was deposited with the ATCC under Accession No. 68720.

Furthermore, as essentially stated in the previous Office Action, in light of the other disclosure of the instant specification that various forms of the extracellular domain of LFA-3 may be fused to the Fc domain of an immunoglobulin, which the skilled artisan would also consider to be "LFA3TIP" fusion proteins (see, in particular page 84, 3rd paragraph to page 85, 1st paragraph) it is yet further unclear what is meant by the claimed limitation, "wherein the fusion protein is LFA3TIP", and if applicant does not understand what is being claimed then applicant cannot possibly make and use the claimed biological material.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **Claims 6, 7, 26-31, 33-36, 39, 40, 62, 63, 66, 69 and 72-75 are rejected under 35 U.S.C. 103(a)** as being unpatentable over **Bazin et al.** (WO 99/03502) in view of **Wallner et al.** (USSN 6,162,432), **Branco et al.** (Transplantation. 1999 Nov 27;68(10):1588-96)(each of which was cited on applicant's IDS of November 21, 2003), **Le et al.** (USSN 6,277,969) and **Strom et al.** (Therapeutic Immunology edited by Austen et al., Blackwell Science, Cambridge, MA, 1996; see pages 451-456)(see entire documents).

This is a New Grounds of Rejection necessitated by applicant's amendment to the claims.

With respect to newly added claims 72-75, the limitations of these claims are taught by the previously applied references. For example, Branco teaches that MEDI-507 acts to suppress the immune response by suppressing the proliferation of and inducing lysis of activated T cells (see, in particular, Results pages 3-11 as renumbered by the examiner, including page 5, 1st paragraph and page 9, 2nd paragraph), it would have been obvious to one of ordinary skill in the art to monitor the mean absolute lymphocyte count when treating an autoimmune or inflammatory disorder with MEDI-507 and one or more anti-angiogenic agents, such as anti-TNFα antibody. In particular, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to measure the mean absolute lymphocyte count in the patient being treated to determine if an effective amount of MEDI-507 were being administered.

With respect to applicant's argument concerning the applied references, applicant's arguments have been considered but has not been found convincing, essentially for the reasons of record.

With respect to Bazin, applicant argues, in essence, that while Bazin teaches the combination of anti-CD2 antibody and other generic "techniques, drugs or compounds" to inhibit T-cell activation, Bazin does not teach methods of inhibiting T cell activation comprising administering the *specific combination* of molecules now claimed, i.e., administration of MEDI-507 or LFA3TIP in conjunction with REMICADE® or ENBREL®.

Applicant's argument has been considered but has not been found convincing, essentially for the reasons of record.

With respect to applicant's argument concerning inhibiting T cell activity by administering a CD2 binding agent and ***ENBREL***, applicant is essentially arguing a limitation not currently under examination as ENBREL is receptor fusion protein not an antibody and thus it is not the elected species of "anti-angiogenic agent", which is an "anti-TNFα antibody".

Moreover, with respect to applicant's argument concerning Bazin's teachings about the administration of the combination of MEDI-507 and REMICADE®, or LFA3TIP and REMICADE®, one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In particular, with respect to treating/ameliorating one or more symptoms of an autoimmune or inflammatory disorder, such as psoriasis, by administering to a subject a therapeutically effective amount of one or more CD2 binding molecules, ***wherein at least one CD2 binding molecule is MEDI-507***, and a therapeutically effective amount of one or more anti-angiogenic agents ***wherein at least one anti-angiogenic agent is the anti-TNFα antibody REMICADE®***, one cannot show nonobviousness by attacking Bazin without reference to the teachings of, for example, Wallner, Branco, Le and Strom, which teach, essentially as stated in the previous Office Action,

- that "MEDI-507 is being investigated for use in autoimmune and other chronic inflammatory conditions such as psoriasis" (Branco);

- that T11$_2$ anti-CD2 antibodies which do not inhibit the interaction between CD2 and LFA-3, such as the MEDI-507 antibody taught by Branco, can be used to treat psoriasis (Wallner),

- that the anti-TNFα antibody cA2, also known as REMICADE®, can be used to treat diseases related to angiogenesis such as psoriasis (Le); and

- that each of these references teach the general concept of combining multiple immunosuppressive agents to treat a given autoimmune or inflammatory disorder, a concept well understood by one of ordinary skill in the art as of applicant's earliest claimed priority date as evidenced by the teachings of Strom et al. that the simultaneous use of several immunosuppressive agents promotes additive-synergistic effects which allow for lower individual dosages and therefore lower toxicity.

Given the teachings above in combination with the teachings of Bazin, essentially as stated in the previous Office Action, that MEDI-507 can be used to treat an autoimmune or inflammatory disorder or ameliorating one or more symptoms thereof, at various effective doses depending upon patient response, and in combination with other agents that inhibit T cell activation, such as other CD2 binding agents, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to practice the instant claims.

Likewise, with respect to treating/ameliorating one or more symptoms of an autoimmune or inflammatory disorder, such as psoriasis, by administering to a subject a therapeutically effective amount of one or more CD2 binding molecules, ***wherein at least one CD2 binding molecule is LFA3TIP***, and a therapeutically effective amount of one or more anti-angiogenic agents ***wherein at least one anti-angiogenic agent is the anti-TNFα antibody REMICADE®***, one cannot show nonobviousness by attacking Bazin without reference to the teachings of, for example, Wallner, Le and Strom, which teach, essentially as stated in the previous Office Action,

- that LFA3TIP can be used to treat psoriasis (Wallner);

- that the anti-TNFα antibody cA2, also known as REMICADE®, can be used to treat diseases related to angiogenesis such as psoriasis (Le); and

- that each of these references teach the general concept of combining multiple immunosuppressive agents to treat a given autoimmune or inflammatory disorder, a concept well understood by one of ordinary skill in the art as of applicant's earliest claimed priority date as evidenced by the teachings of Strom et al. that the simultaneous use of several immunosuppressive agents promotes additive-synergistic effects which allow for lower individual dosages and therefore lower toxicity.

Applicant further argues that the secondary references do not cure the alleged "deficiencies" of Bazin for a variety of reasons.

Applicant's arguments have been considered but have not been found convincing, essentially for the reasons of record.

For example, with respect to the teachings of Wallner and the teachings of Le, applicant fails to address the teachings of these references that LFA3TIP can be used to treat psoriasis (Wallner) and that anti-TNFα antibody cA2, also known as REMICADE®, can be used to treat diseases related to angiogenesis such as psoriasis (Le). Instead, applicant asserts, in essence, that because both references teach a variety of embodiments, and because neither reference specifically teaches the claimed invention, it would not have been obvious to one of ordinary skill in the art to arrive at the claimed invention from the reference teachings.

Again, one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

Moreover, applicant is reminded that as stated in MPEP § 2123, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Also, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied,* 493 U.S. 975 (1989).

Furthermore, with respect to the teachings of Branco, Applicant argues that "[c]ontrary to the Examiner's contention, Branco does not teach or suggest combining MEDI-507 with other biological or chemical agents with differing modes of action for the treatment of an autoimmune disorder or an inflammatory disorder," and quotes the last sentence of Branco which states that the "combination of MEDI-507 and other biological or chemical agents with differing modes of action could induce ***long-term tolerance to foreign tissue.***" (emphasis added). Therefore, applicant concludes, "in view of the teaching in Branco, it would not have been obvious to one of ordinary skill in the art to select the combination of a CD2 binding molecule, such as MEDI-507 or LFA3TIP, and an anti-angiogenic agent, such as REMICADE® or ENBREL® for the ***treatment of an autoimmune disorder or an inflammatory disorder***."

Applicant's argument has been considered but has not been found convincing, essentially for the reasons of record.

The teachings of Branco are not limited to the last sentence. As mentioned above, Branco teaches that MEDI-507 can be used to treat psoriasis. Branco further teaches that at lower concentrations, at least in vitro, MEDI-507 both suppresses the proliferation of and induces lysis of activated T cells (see, in particular, Results pages 3-11 as renumbered by the examiner, including page 5, 1st paragraph and page 9, 2nd paragraph). Thus, based on the teachings of Branco, MEDI-507 can be expected to be useful in treating autoimmune or inflammatory disorders, such as psoriasis, by suppressing the proliferation of and inducing the lysis of activated T cells. In contrast, as taught by Le, anti-TNFα antibody treats diseases related to angiogenesis such as psoriasis by suppressing the pro-inflammatory/pro-angiogenic cytokine TNFα. Given that each of the applied references teach the general concept of combining multiple immunosuppressive agents to treat a given autoimmune or inflammatory disorder, a concept well understood by one of ordinary skill in the art as of applicant's earliest claimed priority date, as evidenced by Strom which teaches the general concept that simultaneous use of several immunosuppressive agents promotes additive-synergistic effects which allow for lower individual dosages and therefore lower toxicity, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to combine the MEDI-507 antibody of Branco/Bazin or the LFA3TIP fusion protein of Wallner with the anti-TNFα antibody of Le to treat psoriasis.

Furthermore, it was prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Applicant further argues that the Examiner's citation of five references to reject the claims as obvious indicates that the rejection is weak, that there is no suggestion or motivation to combine the reference teachings, and that the Examiner is improperly relying on hindsight reasoning to arrive at the claimed invention.

However, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See In re Gorman, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). In addition, nothing of record would indicate that it would have been nonobvious to employ those teachings. That the teachings relied upon were repeated in a number of references serves to further strengthen the conclusion of obviousness.

Moreover, in response to applicant's argument that there is no suggestion or motivation to combine the reference teachings without relying on hindsight reasoning, it should be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Furthermore, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See MPEP § 2145 and Pfizer, Inc. v. Apotex, Inc. (06-1261), "a suggestion, teaching, or motivation to combine the relevant prior art teachings to achieve the claimed invention does not have to be found explicitly in the prior art references sought to be combined, but rather 'may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself.'" DyStar, 464 F.3d at 1361; see also Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1307-08 (Fed. Cir. 2006).

Given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the instant claims are unpatentable over Bazin in view of Wallner, Branco, Le and Strom.

11. Claims **6, 7, 26-28, 31, 33-36, 39, 66 and 75** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **37-39 and 42** of copending USSN 10/091,236.

This is a New Grounds of Rejection necessitated by applicant's amendment to the claims as well as recent amendments to the claims of USSN 10/091,236.

The claims of USSN 10/091,236 recite a method of treating an autoimmune disorder or inflammatory disorder or ameliorating one or more symptoms thereof, said method comprising administering to a subject in need thereof a therapeutically effective amount of one or more integrin $\alpha_v\beta_3$ antagonists and MEDI-507. Given that the instant specification teaches "integrin $\alpha_v\beta_3$ antagonists" are one species of anti-angiogenic agent (see entire document, in particular page 23, 1st paragraph), the claims of the instant application, which recite an "anti-angiogenic agent" are anticipated by the claims of USSN 10/091,236.

This is a provisional obviousness-type double patenting rejection.

It is noted that applicant requests that the provisional double patenting rejection over copending application USSN 10/091,236 be held in abeyance until such time as there is allowable subject matter.

Applicant's request is acknowledged, however Applicant is advised that the instant rejection will be maintained until such time as a terminal disclaimer signed by the assignee and fully compliant with 37 CFR 3.73(b) is submitted.

12. **Claims 6, 7, 26-28, 31, 33-36, 39, 66 and 75** are directed to an invention not patentably distinct from **claims 37-39 and 42** of apparently commonly assigned **USSN 10/091,236**. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). The particular commonly assigned claims discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
June 2, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
1600
6/4/07